control of hyperglycemia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LANTUS (U.S. Patent No. 5,101,013) from Hoechst Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 26, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LANTUS represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LANTUS is 1,591 days. Of this time, 1,227 days occurred during the testing phase of the regulatory review period, while 364 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: December 14, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 14, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 23, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for LANTUS (NDA 21–081) was initially submitted on April 23, 1999.

3. *The date the application was approved*: April 20, 2000. FDA has verified the applicant's claim that NDA 21–081 was approved on April 20, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 976 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 31, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 28, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–10632 Filed 5–31–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0259]

Determination of Regulatory Review Period for Purposes of Patent Extension; X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM. X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with x-ray, magnetic resonance imaging (MRI), and/or computerized tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels. Subsequent to this approval, the Patent and Trademark Office received a patent

term restoration application for X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM (U.S. Patent No. 6,235,030) from St. Francis Medical Technologies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 12, 2006, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM is 2,224 days. Of this time, 1,538 days occurred during the testing phase of the regulatory review period, while 686 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: October 22, 1999. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on February 11, 2000. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on October 22, 1999, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: January 6, 2004. FDA has verified the applicant's claim that the premarket approval application (PMA) for X-STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM (PMA P040001) was initially submitted January 6, 2004.

3. *The date the application was approved*: November 21, 2005. FDA has verified the applicant's claim that PMA P040001 was approved on November 21, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,053 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 31, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 28, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–10618 Filed 5–31–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0282]

Determination of Regulatory Review Period for Purposes of Patent Extension; PHAKIC INTRAOCULAR LENSES

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PHAKIC INTRAOCULAR LENSES and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA approved for marketing the medical device, PHAKIC INTRAOCULAR LENSES. PHAKIC INTRAOCULAR LENSES is indicated for: (1) The reduction or elimination of myopia in adults with myopia ranging from -5 to -20 diopters with less than or equal to 2.5 diopters of astigmatism at the spectacle plane and whose eyes have an anterior chamber depth greater than or equal to 3.2 millimeters; and (2) patients with documented stability of refraction for the prior 6 months, as demonstrated by spherical equivalent change of less than or equal to 0.50 diopters. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration